1 (James Luckett, APRN-C)

Comment: Suggests opening up the B reader program to non-physicians.
Response: Federal regulations (42CFR37.51 external link) specify that only physicians are eligible to be candidates for the B Reader examination.

2 (Hervey Levin)

Comment: Requests the Federal Register cite (sic) for the recommendations for which comments were requested.
Response: No revision is warranted. The announcement requesting comment on the draft web pages was published in the Federal Register: November 17, 2005 (Volume 70, Number 221, Pages 69765-69766). The draft pages were not printed in the Federal Register, but a web address for the draft pages was provided in that announcement.

3 (Steven E. Haber, MD)

Comment: Suggests clarifying the point that pneumoconiosis cannot be diagnosed based on x-ray alone.
Response: We agree, and have now clearly stated this on the page dealing with "Contested Proceedings." Here the text was changed to "As in other settings, it is important to remember that chest radiograph findings alone are insufficient for the diagnosis of pneumoconiosis. Other data, such as the medical and occupational history, the physical examination, additional types of chest imaging, various laboratory tests, and biopsy results should also be considered, as available."

4 (ACOEM)

Comment A: Supports the usefulness of the B Reader Program.
Response A: No revision warranted.

Comment B: Emphasizes that pneumoconiosis cannot be diagnosed based on x-ray alone.
Response B: See response to Commenter #3, above.

Comment C: Suggests that NIOSH should devote further resources to application of digital technologies in the recognition and classification of pneumoconioses.
Response C: We agree with ACOEM and work is in progress towards developing a scientific basis for applying digital chest imaging technologies in the classification of chest radiographs.

5 (William S. Beckett, MD, MPH)

Comment A: Supports the recommendations in the draft.
Response A: No revision warranted.

Comment B: Encourages efforts to develop a standardized system for classifying CT scans for pneumoconiosis.
Response B: We appreciate this comment. High resolution computed tomography (HRCT) scanning of the chest is a very important tool for evaluating pulmonary and pleural disease. However, the scope of the current web site is limited to ILO classification of chest radiographs, which is a well accepted, current practice.

6 (Darrell K. Smith, CIH, MPH)

Comment A: Suggests clarifying the potentially confusing statement, “For medical diagnosis purposes, single radiograph readings are appropriate and do not need to be done as formal International Labour Office (ILO) classifications or by a certified B Reader.”
Response A: We agree and have made revisions to clarify this aspect of the section dealing with the Medical Diagnosis setting.

Comment B: Suggests replacing the term “scoring” with “classification” on pages 1, 5, 6, and 14.
Response B: We agree and now use that terminology throughout.

Comment C: Suggests adding a paragraph and link regarding MSHA reporting of pneumoconioses.
Response C: A description and link have been placed on the page “Classification of Chest Radiographs: Practices for Worker Monitoring and Surveillance.”

7 (Catherine Inman, MD, MPH)

Comment: Provides suggestions for improving dissemination of draft for comment.
Response: We appreciate these comments. In soliciting a second round of comments on the revised web site, we will specifically reach out to current B readers.

8 (Lester Brickman)

Comment: Asserts that the NIOSH ‘Code of Ethics for B Readers’ is necessary but insufficient. To “add some teeth to NIOSH’s ‘Ethical Considerations for B Readers,’ NIOSH should audit “B-reads” prepared for litigation based on “presentation of a credible complaint that a litigation B Reader’s interpretations depart substantially from ILO standards,” and remove certification if the reader fails the audit.
Response: In the revised web site, we have focused efforts on addressing the primary goal of achieving reliable radiograph classification. We believe that one of the most important components of reliable classification is selection of readers who are mainstream in their classification tendencies. We provide recommendations in the revised web site to optimize the chances that mainstream readers are utilized and to minimize the impact of extreme readers. To further minimize impact of extreme readings, we provide recommendations for use of multiple readers in appropriate settings. And we provide recommendations concerning “blinding” of readers in appropriate settings. We believe that these recommendations will be more effective in assuring accurate radiograph classification than an audit system. Still, we are concerned about incompetent or unethical behavior by physicians. As noted in the B reader Code of Ethics, "B readers shall promptly report to the National Institute for Occupational Safety and Health, B Reader Certification Program any revocation or suspension of a medical license, voluntary relinquishment of a medical license or conversion to inactive status, or the voluntary surrender of a medical license while under investigation." As noted in “The NIOSH B Reader Certification Program” web page, under the subheading “Comments or Concerns”: “Classifying chest radiographs is practicing medicine…Physicians should not classify chest films and may not take either the B reader certification examination or quadrennial recertification examinations unless they possess a current, active license to practice medicine.” NIOSH strongly encourages those with concerns about specific medical practitioners to bring these concerns to the relevant State Medical Licensing Boards, which have strong capabilities to investigate and discipline physicians.

9 (Allan R. Golstein, MD)

Comment A: Suggests adding a list of providers who are available for management of occupational lung disease.
Response A: This comment is now moot. The relevant paragraph on disease management was removed because it was peripheral to the intent of these web pages.

Comment B: Disagrees with assertion that coal mine dust exposure can cause emphysema and hopes that a statement in the draft indicating that it does cause emphysema "does not allow attorneys … to base their arguments on [this as] 'NIOSH policy.'"
Response B: This example has been deleted from the revision, but not because we agree with the commenter. In act, NIOSH has cited evidence for occupational exposure to coal mine dust as an etiology of emphysema in its "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust'(1995).

10 (Laura S. Welch, MD)

Comment A: The last provision of the Code of Ethics for B Readers, which states that B Readers shall inform NIOSH of changes in their medical licensure, should be deleted. It is potentially burdensome for B Readers and, given the apparent lack of a requirement that B Readers be licensed to practice medicine, does not add value to the Code of Ethics.
Response A: As noted in response to Commenter #1, federal regulations (42CFR37.51) specify that only physicians are eligible to be candidates for the B Reader examination. A statement specifying that NIOSH requires all examination candidates to hold a currently valid and active medical license has been inserted in "The NIOSH B Reader Certification Program" web page, under the subheading "Comments or Concerns."

Comment B: Suggests that, if the last provision of the Code of Ethics for B Readers is not deleted, NIOSH put in writing what will happen when a B Reader reports loss of active licensure.
Response B: As noted in "The NIOSH B Reader Certification Program" web page, under the subheading "Comments or Concerns": "Classifying chest radiographs is practicing medicine…Physicians should not classify chest films and may not take either the B reader certification examination or quadrennial recertification examinations unless they possess a current, active license to practice medicine."

11 (Coalition for Litigation Justice, Inc., et al.)

Comment A: Suggests that NIOSH establish a program for auditing B Readers to include: a) an annual questionnaire to be answered by B Readers concerning their B reading practices with removal of B Readers who do not return the questionnaire or who falsify their responses; b) re-classification of chest x-rays upon which diagnoses of silicosis were based and which are in the custody of the United States District Court for the Southern District of Texas in a case presided over by Judge Janis Graham Jack, with potential decertification of the B Readers who initially classified the films for litigation purposes based on a comparison of their classifications with those of an expert panel; c) a requirement for B Readers to submit to NIOSH (deidentified) results of each classification done for purposes of litigation or compensation, so that NIOSH can use this data to select a sample of B Readers who would be required to

submit the original chest x-rays and their classifications thereof, with potential decertification of the B Readers who initially classified the films for litigation purposes based on a comparison of their classifications with those of an expert panel; and d) establishment by NIOSH of a procedure by which audits similar to the preceding could be requested by a third party. If NIOSH is not willing to establish such a program, then the B Reader Program should be considered for termination and NIOSH could better apply its funds for public health purposes and let the courts devise their own means for establishing the expertise of physicians providing ILO classifications.
Response A: As noted in response to Commenter #8, in the revised web site, we have focused efforts on addressing the primary goal of achieving reliable radiograph classification. We believe that one of the most important components of reliable classification is selection of readers who are mainstream in their classification tendencies. We provide recommendations in the revised web site to optimize the chances that mainstream readers are utilized and to minimize the impact of extreme readers. We believe that these recommendations will be more effective in assuring accurate radiograph classification than an audit system. It may be entirely appropriate for the courts, to make use of this guidance in an effort to establish quality of B Reader ILO classifications and qualifications of expert B Reader witnesses. The court might choose to ask pertinent and specific questions about how the ILO classifications for a particular case were obtained and about the B Readers who provided them. Concerns about specific B Readers can and should be referred to the appropriate State Board of Medicine (as addressed in the response to Commenter #8).

Comment B: Suggests that, through its long-standing relationship with the American College of Radiology, NIOSH should establish an independent Panel of Expert in Pneumoconiosis Radiology to serve as court-appointed experts.
Response B: No revision is warranted. While providing general guidelines in these revised web pages, it is not our intent to so directly be involved in supporting the legal system. Courts are free to contact the American College of Radiology's Committee on Pneumoconiosis (aka Task Force on Pneumoconiosis) to request that suitable members serve in the suggested capacity.

Comment C: Suggests that NIOSH assure that: a) B Readers classifying chest radiographs for purposes of litigation or compensation are providing the results to the claimants in a medically acceptable manner; or, b) when providing their classifications to other medical professionals for diagnostic purposes, they take steps to assure that those other medical professionals provide the results to their patients.
Response C: The B Reader's obligation to assure prompt reporting of findings to examinees is directly addressed in the section entitled "Ethical Considerations for B Readers." In addition, the web page providing guidelines for each setting has been revised and includes a section entitled "Notification."

Comment D: Suggest that the Code of Ethics for B Readers make clear that diagnoses, especially for purposes of litigation and compensation, are not to be made on the basis of the chest radiograph alone.
Response D: The revised "Contested Settings" page now clearly states that "chest radiograph findings alone are insufficient for the diagnosis of pneumoconiosis" (See response to Commenter # 3).

Comment E: Asserts that the draft does not address "the application of the ILO system in litigation by B Readers. NIOSH should redraft the recommendations with guidance for application in the legal setting and re-post for additional comments..."

Response E: A new "Recommended Practices for Reliable Classification of Chest Radiographs by B Readers" page has been added. It provides a summary of specific recommendations on real-world approaches for eliminating abuses and assuring accurate radiograph classification in various settings, including contested proceedings. Also, an expanded discussion of issues and approaches for contested proceedings is provided on the new "Classification of Chest Radiographs: Practices in Contested Proceedings" page.

Comment F: Suggests that "NIOSH should cite references regarding the controversial use of the ILO System in the non-research setting."
Response F: A reference to the controversy (Ducatman '91) is included on the "Issues in Classification of Chest Radiographs" page.

Comment G: Urges NIOSH to allocate funds to develop standard sets of "calibration films" that could be purchased by others for use in quality assurance of ILO classifications.
Response G: No revision warranted. NIOSH researchers are currently in the process of developing a set of calibration radiographs for use in the Coal Workers' X-ray Surveillance Program administered by NIOSH. At this time, there are no current plans for reproducing the set for broader distribution, but this may be considered at a future point in time.

Comment H: Questions appropriateness of the paragraph providing guidance on how workers with symptoms should seek medical care.
Response H: We agree and have removed this paragraph as being peripheral to the intent of the web pages.

Comment I: Asserts that is inappropriate to include "population surveillance" with "research" given that content related to "population surveillance" is found exclusively in the section on worker monitoring.
Response I: We agree and the revised pages do not mention "population surveillance" in the page dealing with "Epidemiologic Research," restricting it to the page dealing with "Worker Monitoring and Surveillance."

Comment J: Suggests adding a reference to the AMA guides to the Evaluation of Permanent Impairment.
Response J: Reference to this document was added to the page, "Classification of Chest Radiographs: Practices in Contested Proceedings," first paragraph.

12 (Jerome F. Wiot)

Comment: Supports the Code of Ethics for B Readers, but urges NIOSH to go beyond this and establish a system for auditing performance of B Readers accused by others of improprieties of reading so as to remove those B Readers who violate the intent of the Code.
Response: See response to Commenter #8.

13 (American Minerals Association)

Comments: Comments are identical to those offered by Commenter #11.
Responses: See responses to Commenter #11.